Adverse Event Report

SMITH & NEPHEW, INC. ORTHOPAEDIC DIV. ECHELON FEMORAL COMPONENT

back to search results

Catalog Number 71340214
Event Date 04/04/2007
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Manufacturer Narrative
Na.

Event Description
It was reported that revision surgery was performed due to a fracture of the device.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	FEMORAL COMPONENT
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC. ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC. ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW, INC. 1450 Brooks Rd. Memphis TN 38116
Manufacturer Contact	Melanie Travis 1450 Brooks Rd. Memphis , TN 38116 (901) 399 -6233

Device Event Key	867772
MDR Report Key	888917
Event Key	851293
Report Number	1020279-2007-00175
Device Sequence Number	1
Product Code	KWY
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	UNKNOWN
Type of Report	Initial
Report Date	07/05/2007
***1* Device Was Involved In the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	08/03/2007
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340214
Device LOT Number	81108343R
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Event Location	Hospital
Was The Report Sent To Manufacturer?	No
Date Manufacturer Received	07/05/2007
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	No
Type of Device Usage	Initial

Database last updated on July 31, 2008

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON ROD back to search results

Catalog Number 71340413
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Event Description
It was reported that revision surgery was performed due to a fracture in the device.

Manufacturer Narrative
Na.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	ROD
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW, INC. 1450 Brooks Rd. Memphis TN 38116
Manufacturer Contact	Melanie Travis, Reg Compliance 1450 Brooks Rd. Memphis , TN 38116 (901) 399 -6233
Device Event Key	864668

MDR Report Key	885872
Event Key	848264
Report Number	1020279-2007-00170
Device Sequence Number	1
Product Code	HSB
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	06/29/2007
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	07/27/2007
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340413
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was The Report Sent To Manufacturer?	No
Date Manufacturer Received	06/29/2007
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	No
Type of Device Usage	Initial

Database last updated on July 31, 2008

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON FEMORAL COMPONENT

back to search results

Catalog Number 71310312
Event Date 12/05/2006
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Event Description
It was reported that revision surgery was performed due to the breaking of the femoral component.

Manufacturer Narrative
Na.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	FEMORAL COMPONENT
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW, INC. 1450 Brooks Rd. Memphis TN 38116
Manufacturer Contact	Melanie Travis 1450 Brooks Rd. Memphis , TN 38116

	(901) 399 -6233
Device Event Key	855797
MDR Report Key	874996
Event Key	771776
Report Number	1020279-2007-00152
Device Sequence Number	1
Product Code	HSA
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	06/04/2007
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	07/05/2007
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71310312
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was The Report Sent To Manufacturer?	No
Date Manufacturer Received	06/04/2007
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	No
Type of Device Usage	Initial

Database last updated on July 31, 2008

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH
3500A Facsimile

Smith & Nephew, Inc., Orthopaedic Division

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Reisys International Inc., FDA Facsimile Approval: 2/16/1999

Mfr Report # _____

Usr/Importer Report # 1020279-2007-00036

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier: C.D. In confidence
2. Age at Time of Event: or UNK Date of Birth: 01/24/52
3. Sex: [X] Female [ ] Male
4. Weight: UNK lbs or UNK kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [X] Adverse Event and/or [ ] Product Problem (e.g., defects/malfunctions)
2. Outcomes Attributed to Adverse Event (Check all that apply)
   - [ ] Death (mm/dd/yyyy)
   - [ ] Life-threatening
   - [X] Hospitalization - initial or prolonged
   - [X] Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - [ ] Disability or Permanent Damage
   - [ ] Congenital Anomaly/Birth Defect
   - [ ] Other Serious (Important Medical Events)
3. Date of Event (mm/dd/yyyy): 01/30/2007
4. Date of This Report (mm/dd/yyyy): 02/28/2007
5. Describe Event or Problem

It was reported that revision surgery was performed due to breakage of the device.

6. Relevant Tests/Laboratory Data, Including Dates

UNK

7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

UNK

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer, or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler)
   # 1.
   # 2.
2. Dose, Frequency & Route Used
   # 1.
   # 2.
3. Therapy Dates (If unknown, give duration) from/to (or best estimate)
   # 1.
   # 2.
4. Diagnosis for Use (Indication)
   # 1.
   # 2.
5. Event Abated After Use Stopped or Dose Reduced?
   # 1. [ ] Yes [ ] No [ ] Doesn't Apply
   # 2. [ ] Yes [ ] No [ ] Doesn't Apply
6. Lot #
   # 1.
   # 2.
7. Exp. date
   # 1.
   # 2.
8. Event Reappeared After Reintroduction?
   # 1. [ ] Yes [ ] No [ ] Doesn't Apply
   # 2. [ ] Yes [ ] No [ ] Doesn't Apply
9. NDC # or Unique ID
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name: Femoral Stem
2. Common Device Name: Echelon
3. Manufacturer Name, City and State: Smith & Nephew Inc., Orthopaedic Div. 1450 Brooks Road Memphis, TN 38116 USA
4. Model #: NA
   Lot #: 90803889
   Catalog #: 71340813
   Expiration Date (mm/dd/yyyy): UNK
   Serial #: NA
   Other #: NA
5. Operator of Device: [X] Health Professional [ ] Lay User/Patient [ ] Other:
6. If Implanted, Give Date (mm/dd/yyyy): 08/10/2000
7. If Explanted, Give Date (mm/dd/yyyy): 01/30/07
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? [ ] Yes [X] No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA) [ ] Yes [ ] No [X] Returned to Manufacturer on 02/16/2007 (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

UNK

E. INITIAL REPORTER

1. Name and Address
   George Orza, Smith & Nephew, Inc. 1800 S. Canyon Park Circle, Suite 102 Edmond, OK 73013, USA
   Phone # 405-330-0040
2. Health Professional? [ ] Yes [X] No
3. Occupation: Sales Rep
4. Initial Reporter Also Sent Report to FDA: [ ] Yes [ ] No [X] Unk.

Smith & Nephew, Inc., Orthopaedic Division

MEDWATCH
3500A Facsimile (Back) *(continued)*

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One: ☐ User Facility ☐ Importer
2. UF/ Importer Report Number
3. User Facility or Importer Name/Address
4. Contact Person
5. Phone Number
6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)
7. Type of Report: ☐ Initial ☐ Follow-up #
8. Date of This Report (mm/dd/yyyy)
9. Approximate Age of Device
10. Event Problem Codes (Refer to coding manual): Patient Code; Device Code
11. Report Sent to FDA? ☐ Yes ☐ No (mm/dd/yyyy)
12. Location Where Event Occurred: ☐ Hospital ☐ Outpatient Diagnostic Facility ☐ Home ☐ Nursing Home ☐ Ambulatory Surgical Facility ☐ Outpatient Treatment Facility ☐ Other: (Specify)
13. Report Sent to Manufacturer? ☐ Yes ☐ No (mm/dd/yyyy)
14. Manufacturer Name/Address

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event: ☐ Death ☒ Serious injury ☐ Malfunction ☐ Other:
2. If Follow-up, What Type? ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. Device Evaluated by Manufacturer? ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☒ No (Attach page to explain why not) or provide code: 02
4. Device Manufacture Date (mm/yyyy): 08/1999
5. Labeled for Single Use? ☒ Yes ☐ No
6. Evaluation Codes (Refer to coding manual): Method; Results; Conclusions
7. If Remedial Action Initiated, Check Type: ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Other: ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/ Adjustment
8. Usage of Device: ☒ Initial Use of Device ☐ Reuse ☐ Unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:
10. ☐ Additional Manufacturer Narrative and/or
11. ☐ Corrected Data

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)

Mrs. Melanie Travis, Reg Compliance
Smith & Nephew, Inc., Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116 USA
Site: Smith & Nephew Inc., Orthopaedic Div.
1450 Brooks Road
Memphis, TN 38116 USA

2. Phone Number: (901) 399-5233
3. Report Source (Check all that apply): ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☒ Company Representative ☐ Distributor ☐ Other
4. Date Received by Manufacturer (mm/dd/yyyy): 01/31/2007
5. (A)NDA # / IND # / STN# / PMA/ 510(k) # / Combination Product ☐ Yes / Pre-1938 ☐ Yes / OTC Product ☐ Yes
6. If IND, Give Protocol #
7. Type of Report (Check all that apply): ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☒ Initial ☐ 15-day ☐ Follow-up #
8. Adverse Event Term(s)
9. Manufacturer Report Number: 1020279-2007-00036

Smith & Nephew, Inc., Orthopaedic Division

MEDWATCH
3500A Facsimile (Back) *(continued)*

Page 3 of 3

MW Report #

UF/Importer Report # 1020279-2007-00036

FDA Use Only

ADDITIONAL INFORMATION

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON FEMORAL COMPONENT

back to search results

Catalog Number 71340513
Event Date 10/10/2005
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Event Description
It was reported that patient underwent revision surgery due to pain.

Manufacturer Narrative
Na.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	FEMORAL COMPONENT
Baseline Brand Name	ECHELON
Baseline Generic Name	FEMORAL COMPONENT
Baseline Catalogue Number	71340513
Other Baseline ID Number	UNK
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Road Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Road Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW INC. 1450 Brooks Road

	Memphis TN 38116
Manufacturer Contact	Nicholas Tabrizi, Specialist 1450 Brooks Road Memphis , TN 38116 (901) 399 -6017
Device Event Key	780342
MDR Report Key	792702
Event Key	756512
Report Number	1020279-2006-00671
Device Sequence Number	1
Product Code	JDI
Report Source	Manufacturer
Source Type	Other
Reporter Occupation	Physician
Type of Report	Initial
Report Date	12/08/2006
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	12/08/2006
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340513
Device LOT Number	80207118
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	Yes
Was the Report Sent to FDA?	No
Date Manufacturer Received	11/09/2006
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	Yes
Is this an Explanted Device?	
Type of Device Usage	Initial

Database last updated on July 31, 2008

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON FEMORAL COMPONENT

back to search results

Catalog Number 71340613
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Event Description
It was reported that the stem broke in vivo.

Manufacturer Narrative
Na.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	FEMORAL COMPONENT
Baseline Brand Name	ECHELON
Baseline Generic Name	FEMORAL STEM
Baseline Catalogue Number	71340613
Baseline Device Family	ECHELON POROUS REVISION HIP SYSTEM
Baseline Device 510(K) Number	K963486
Baseline Device PMA Number	
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	11/27/1996
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd.

	Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW INC. 1450 Brooks Road Memphis TN 38116
Manufacturer Contact	Nicholas Tabrizi, Specialist 1450 Brooks Road Memphis , TN 38116 (901) 399 -6017
Device Event Key	780350
MDR Report Key	792710
Event Key	756520
Report Number	1020279-2006-00670
Device Sequence Number	1
Product Code	JDI
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	UNKNOWN
Type of Report	Initial
Report Date	12/08/2006
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	12/08/2006
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340613
Device LOT Number	01KM01503
Was Device Available For Evaluation?	Device Returned To Manufacturer
Date Returned to Manufacturer	11/08/2006
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	11/09/2006
Was Device Evaluated By Manufacturer?	No

Date Device Manufactured	10/01/2001
Is The Device Single Use?	No
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	Yes
Is this an Explanted Device?	Unknown
Type of Device Usage	Initial

Database last updated on July 31, 2008

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON FEMORAL COMPONENT

back to search results

Catalog Number 71340117
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Event Description
It was reported that revision surgery was performed due to fracture.

Manufacturer Narrative
Na.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	FEMORAL COMPONENT
Baseline Brand Name	ECHELON
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	71340117
Baseline Device Family	ECHELON HIP SYSTEM
Baseline Device 510(K) Number	K963486
Baseline Device PMA Number	
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA
Date First Marketed	11/27/1996
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116

Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW, INC. 1450 Brooks Rd Memphis TN 38116
Manufacturer Contact	Nicholas Tabrizi, Specialist 1450 Brooks Rd Memphis , TN 38116 (901) 399 -6017
Device Event Key	773026
MDR Report Key	785231
Event Key	749302
Report Number	1020279-2006-00656
Device Sequence Number	1
Product Code	JDH
Report Source	Manufacturer
Source Type	Other
Reporter Occupation	Patient
Type of Report	Initial
Report Date	11/17/2006
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	11/17/2006
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340117
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	10/19/2006
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	Yes

Is this an Explanted Device?

Type of Device Usage Initial

Database last updated on July 31, 2008

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON FEMORAL STEM

back to search results

Catalog Number 71340414
Event Date 08/08/2006
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Event Description
It was reported that revision surgery was performed on broken stem.

Manufacturer Narrative
Na.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	FEMORAL STEM
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Road Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Road Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW INC. 1450 Brooks Road Memphis TN 38116
Manufacturer Contact	Nicholas Tabrizi, Specialist 1450 Brooks Road Memphis , TN 38116 (901) 399 -6017

Manufacturer and User Facility Device Experience (MAUDE) [illegible]

Device Event Key	745458
MDR Report Key	757561
Event Key	722153
Report Number	1020279-2006-00582
Device Sequence Number	1
Product Code	KWY
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	09/05/2006
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	09/05/2006
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340414
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	08/10/2006
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Is The Device Single Use?	No
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	Yes
Is this an Explanted Device?	
Type of Device Usage	Initial

Database last updated on July 31, 2008

FDA U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV ECHELON FEMORAL COMPONENT

back to search results

Catalog Number 71340111
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Event Description
It was reported that revision was performed due to pain.

Manufacturer Narrative
Na.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	FEMORAL COMPONENT
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW INC, 1450 Brooks Rd Memphis TN 38116
Manufacturer Contact	Nicholas Tabrizi, Specialist 1450 Brooks Rd Memphis , TN 38116 (901) 399 -6017
Device Event Key	732448

MDR Report Key	744641
Event Key	709634
Report Number	1020279-2006-00564
Device Sequence Number	1
Product Code	JWH
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	UNKNOWN
Type of Report	Initial
Report Date	07/06/2006
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	08/04/2006
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340111
Was Device Available For Evaluation?	Yes
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	07/06/2006
Was Device Evaluated By Manufacturer?	No
Is The Device Single Use?	No
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	Yes
Is this an Explanted Device?	
Type of Device Usage	Initial

Database last updated on July 31, 2008

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV ECHELON FEMORAL STEM

back to search results

Catalog Number 71340111
Event Date 06/06/2006
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Manufacturer Narrative
Na.

Event Description
Revision surgery was performed due to pain.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	FEMORAL STEM
Baseline Brand Name	ECHELON
Baseline Generic Name	FEMORAL STEM
Baseline Catalogue Number	71340111
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW, INC. 1450 Brooks Rd Memphis TN 38116

Manufacturer Contact	Nicholas Tabrizi, Specialist 1450 Brooks Rd Memphis , TN 38116 (901) 399 -6017
Device Event Key	720478
MDR Report Key	732170
Event Key	697465
Report Number	1020279-2006-00547
Device Sequence Number	1
Product Code	KWY
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Physician
Type of Report	Initial
Report Date	06/06/2006
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	07/06/2006
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Invalid Data
Device Catalogue Number	71340111
Device LOT Number	80806352
Was Device Available For Evaluation?	Yes
Is The Reporter A Health Professional?	Yes
Was the Report Sent to FDA?	No
Date Manufacturer Received	06/06/2006
Was Device Evaluated By Manufacturer?	No
Date Device Manufactured	08/01/1998
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	Yes
Is this an Explanted Device?	Unknown
Type of Device Usage	Invalid Data

Database last updated on July 31, 2008

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON HIP COMPONENT

back to search results

Catalog Number 71342011
Event Date 10/11/2005
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Event Description
The pt underwent revision surgery, due to a fracture of the stem component.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	HIP COMPONENT
Baseline Brand Name	ECHELON
Baseline Generic Name	HIP COMPONENT
Baseline Catalogue Number	71342011
Other Baseline ID Number	UNK
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW INC. 1450 Brooks Road Memphis TN 38116
	Rayan Lemelle, Specialist I 1450 Brooks Road

Manufacturer Contact	Memphis , TN 38116 (901) 399 -5899
Device Event Key	632932
MDR Report Key	643424
Event Key	611919
Report Number	1020279-2005-00368
Device Sequence Number	1
Product Code	JDI
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Physician
Type of Report	Initial
Report Date	10/26/2005
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	10/28/2005
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71342011
Device LOT Number	03AM06708A
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	Yes
Was the Report Sent to FDA?	No
Date Manufacturer Received	10/21/2005
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Date Device Manufactured	01/01/2003
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	Yes
Is this an Explanted Device?	
Type of Device Usage	Initial

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON HIP STEM

back to search results

Catalog Number 71340713
Event Date 06/10/2005
Event Type Injury **Patient Outcome** Hospitalization; Other Required Intervention
Event Description
Revision of broken echelon porous stem.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	HIP STEM
Baseline Brand Name	ECHELON
Baseline Generic Name	HIP STEM
Baseline Catalogue Number	71340713
Baseline Model Number	UNK
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 E. Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. 1450 E. Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW INC. 1450 Brooks Road Memphis TN 38116
	Ryan Lemelle Specialist I 1450 Brooks Road

Manufacturer Contact	Memphis , TN 38116 (901) 399 -5899
Device Event Key	613791
MDR Report Key	624144
Event Key	593176
Report Number	1020279-2005-00316
Device Sequence Number	1
Product Code	KWY
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial,Followup
Report Date	07/05/2005,08/03/2005
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	08/04/2005
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340713
Was Device Available For Evaluation?	Device Returned To Manufacturer
Date Returned to Manufacturer	07/21/2005
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	19 mo
Event Location	Hospital
Date Manufacturer Received	07/05/2005
Was Device Evaluated By Manufacturer?	Yes
Date Device Manufactured	10/01/1999
Is The Device Single Use?	No
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	Yes
Is this an Explanted Device?	
Type of Device Usage	Initial

Database last updated on July 31, 2008

Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV ECHELON HIP STEM back to search results

Event Date 01/29/2001
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Event Description
It was reported that revision surgery was necessary due to a dislocation.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	HIP STEM
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC., ORTHOPAEDIC DIV 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW INC. 1450 Brooks Road Memphis TN 38116
Manufacturer Contact	Phillip Emmert, Specialist 1450 Brooks Road Memphis , TN 38116 (901) 399 -5296
Device Event Key	596632
MDR Report Key	606844
Event Key	576709
Report Number	1020279-2005-00219

Device Sequence Number	1
Product Code	JDI
Report Source	Manufacturer
Source Type	Other
Reporter Occupation	Physician
Type of Report	Initial
Report Date	05/25/2005
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	05/25/2005
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	Yes
Was the Report Sent to FDA?	No
Device Age	unknown
Event Location	Hospital
Date Manufacturer Received	05/04/2005
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	Yes
Is this an Explanted Device?	
Type of Device Usage	Initial

Database last updated on July 31, 2008

Adverse Event Report

SMITH & NEPHEW, INC. ECHELON HIP STEM

back to search results

Event Type Injury **Patient Outcome** Hospitalization; Required Intervention

Event Description

It was reported that revision surgery was necessary.

Search Alerts/Recalls

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	HIP STEM
Baseline Device 510(K) Number	
Baseline Device PMA Number	
Manufacturer *(Section F)*	SMITH & NEPHEW, INC. 1450 Brooks Road Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW, INC. 1450 Brooks Road Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW INC. 1450 Brooks Road Memphis TN 38116
Manufacturer Contact	Phillip Emmert, Specialist 1450 Brooks Road Memphis , TN 38116 (901) 399 -5296
Device Event Key	596673
MDR Report Key	606886
Event Key	576749
Report Number	1020279-2005-00218
Device Sequence Number	1
Product Code	JDI

Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Other
Type of Report	Initial
Report Date	05/25/2005
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	05/25/2005
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Device Age	unknown
Event Location	Hospital
Date Manufacturer Received	04/25/2005
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	Yes
Is this an Explanted Device?	Unknown
Type of Device Usage	Initial

Database last updated on July 31, 2008

FDA U.S. Food and Drug Administration

Adverse Event Report

SMITH & NEPHEW INC., ORTHOPAEDIC DIV. ECHELON STEM back to search results

Catalog Number 71340117
Event Date 03/17/2005
Event Type Injury **Patient Outcome** Hospitalization; Required Intervention
Event Description
Revision surgery was performed due to the device fractured.

Search Alerts/Recalls (Contained In Enforcement Reports)
(After selecting, enter device information to search Alerts/Recalls).

new search | submit an adverse event report

Brand Name	ECHELON
Type of Device	STEM
Baseline Brand Name	ECHELON
Baseline Generic Name	HIP PROSTHESIS
Baseline Catalogue Number	71340117
Baseline Device Family	ECHELON HIP SYSTEM
Baseline Device 510(K) Number	K963486
Baseline Device PMA Number	
Baseline Preamendment?	No
Transitional?	No
510(K) Exempt?	No
Shelf Life(Months)	NA

Date First Marketed	11/27/1996
Manufacturer *(Section F)*	SMITH & NEPHEW INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section D)*	SMITH & NEPHEW INC., ORTHOPAEDIC DIV. 1450 Brooks Rd. Memphis TN 38116
Manufacturer *(Section G)*	SMITH & NEPHEW INC. 1450 Brooks Road Memphis TN 38116
Manufacturer Contact	Jason Chamness, Specialist 1450 Brooks Rd Memphis , TN 38116 (901) 399 -6654
Device Event Key	583768
MDR Report Key	593940
Event Key	564453
Report Number	1020279-2005-00188
Device Sequence Number	1
Product Code	JDH
Report Source	Manufacturer
Source Type	Company Representative
Reporter Occupation	Physician
Type of Report	Initial
Report Date	03/17/2005,04/21/2005
***1* Device Was Involved In the Event**	
***1* Patient Was Involved In the Event**	
Date FDA Received	04/21/2005
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	71340117
Device LOT Number	801104075
Was Device Available For Evaluation?	No

Is The Reporter A Health Professional?	Yes
Was the Report Sent to FDA?	No
Distributor Facility Aware Date	03/17/2005
Device Age	63 yr
Event Location	Hospital
Date Manufacturer Received	03/17/2005
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Date Device Manufactured	11/01/1998
Is The Device Single Use?	Yes
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	Yes
Is this an Explanted Device?	
Type of Device Usage	Initial

Database last updated on July 27, 2007